

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PERNIX IRELAND PAIN DAC and  
PERNIX THERAPEUTICS, LLC,

Plaintiffs,

v.

ALVOGEN MALTA OPERATIONS LTD.,

Defendant.

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C.A. No. 16-139-WCB

[REDACTED]

**PUBLIC VERSION FILED: April 16, 2018**

**PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION  
TO STRIKE AND EXCLUDE PERNIX'S INFRINGEMENT THEORY**

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## **I. Introduction**

Alvogen's Motion to Strike ("Motion") (D.I. 125) is without merit and Plaintiffs ("Pernix") respectfully request that it be denied.

As an initial matter, Alvogen's Motion should be denied because it was brought under Federal Rule of Civil Procedure 37(b)(2)(A), which addresses discovery order abuses. As discussed below, Pernix did not violate any discovery order; in fact, as Alvogen admits Pernix timely served infringement contentions and supplements to those contentions. Alvogen's other arguments are also without merit.

First, Pernix did not present a "new" single-actor infringement theory in its Motion for Summary Judgment. Alvogen concedes that Pernix addressed single-actor infringement in its December 2016 infringement contentions, but alleges that Pernix later "made the deliberate decision to drop" that theory in its amended contentions. But Pernix only **added** language in its amended infringement contentions; it did not "drop" anything. Thus, there is no "late-disclosed infringement theory" to be excluded.

Second, even if Pernix's Motion for Summary Judgment "reassert[ed]" a previously dropped infringement theory, Alvogen's Motion should still be denied because exclusion of an infringement theory is an "**extreme sanction**" that normally requires a "showing of willful deception or flagrant disregard of a court order[.]" *Indivior Inc. v. Mylan Techs.*, No. 1:15-cv-1016-RGA, 2017 U.S. Dist. LEXIS 154756, at \*4 (D. Del. Sep. 22, 2017) (emphasis added) (internal quotations removed). Alvogen concedes that it is not accusing Pernix of acting willfully or in bad faith, and Alvogen's Motion should be denied on that basis alone.

Third, Alvogen's Motion should also be denied because none of the *Pennypack* factors support precluding Pernix from arguing single-actor infringement. Alvogen alleges prejudice because its expert did not address infringement by a single actor. But there is nothing for its

expert to address—the potential issue regarding this theory is one of claim interpretation. As explained in Pernix’s Motion for Summary Judgment, if the claims have only a single step of administering, then there is no dispute that the patient performs that step and Alvogen infringes.

Lastly, the Court need not decide Alvogen’s Motion to Strike if it grants Pernix’s summary judgment motion that Alvogen infringes ’760 patent claims 1-4 and 11 as a matter of law under a two-step, joint infringement analysis. Such a finding would render moot Alvogen’s Motion, which only seeks to exclude Pernix from arguing single-actor infringement of those claims.

## **II. Legal Standard**

Alvogen brings its Motion under Federal Rule of Civil Procedure 37(b)(2)(A), which provides sanctions for not obeying a discovery order. Alvogen’s Motion, however, does not explain what discovery order allegedly was violated, or otherwise articulate any basis for moving under Rule 37(b)(2)(A). If Alvogen intended to bring its Motion under Rule 37(c)(1), which sets forth sanctions for failure to disclose or supplement information as required by Rule 26(e), Alvogen’s legal analysis is incomplete. In analyzing whether a party has violated Rule 26(e) by failing to supplement its contentions to disclose new legal theories, Courts in the Third Circuit analyze the four *Tritek* factors before applying *Pennypack*. See *Boehringer Ingelheim Int’l GMBH v. Barr Labs. Inc.*, No. 05-700-JJF, 2008 U.S. Dist. LEXIS 53475, at \*3-5 (D. Del. July 15, 2008). Alvogen’s Motion should be denied because it fails to address the *Tritek* factors.

But, even under Alvogen’s *Pennypack* analysis, its motion fails. “Courts favor the resolution of disputes on their merits[,]” *Abbott Labs. v. Lupin Ltd.*, No. 09-152-LPS, 2011 U.S. Dist. LEXIS 53846, at \*13 (D. Del. May 19, 2011), and “[e]vidence should be excluded sparingly and only in circumstances involving litigation conduct that is clearly unprofessional or inappropriate, and in circumstances creating prejudice to the party against whom the evidence is

offered.” *EON Corp. IP Holdings, LLC v. FLO TV, Inc.*, No. 10-812-RGA, 2013 U.S. Dist. LEXIS 175618, at \*16 (D. Del. Oct. 3, 2013) (internal quotations removed). “[E]xclusion of evidence is a drastic sanction,” only to be imposed if the *Pennypack* factors are satisfied. *De Marines v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1202 (3d Cir. 1978). Those factors include:

- (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded.

*Glaxosmithkline LLC v. Glenmark Pharms. Inc., USA*, No. 14-877-LPS-CJB, 2017 U.S. Dist. LEXIS 21049, at \*5 (D. Del. Feb. 6, 2017) (citing *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-05 (3d Cir. 1977)).

In addition, “[i]t bears emphasis that exclusion of critical evidence,” such as an infringement theory, “is an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.” *Indivior Inc.*, 2017 U.S. Dist. LEXIS 154756, at \*4 (internal quotations removed) (denying motion to strike allegedly new infringement theory); *EON Corp.*, 2013 U.S. Dist. LEXIS 175618, at \*16 (exclusion of “conclusions on infringement” is an extreme sanction); *Abbott Labs.*, 2011 U.S. Dist. LEXIS 53846, at \*8 (exclusion of infringement expert report is an extreme sanction); *AVM Techs., LLC v. Intel Corp.*, No. 15-0033-RGA-MPT, 2016 U.S. Dist. LEXIS 170521, at \*3-7 (D. Del. Dec. 9, 2016) (exclusion of infringement contentions is an extreme sanction); *see also Greatbatch Ltd. v. AVX Corp.*, No. 13-723-LPS, 2015 U.S. Dist. LEXIS 126390, at \*1-4 (D. Del. Sept. 22, 2015) (denying motion to strike allegedly new infringement theory).

### III. Pernix Has Not Raised A New Infringement Theory

Alvogen’s Motion to Strike should be denied because Pernix has not raised a “new” single-actor infringement theory in its Motion for Summary Judgment (D.I. 118, 120). Pernix raised this theory in its Complaint, where it stated that “physicians, health care providers, and/or *patients will directly infringe one or more claims of the ’760 . . . patent[.]*” D.I. 37 at ¶40 (emphasis added), *see also* ¶¶41-42, 48. Pernix again timely raised this theory in its initial contentions served on **December 16, 2016**—almost a year before the end of fact discovery. D.I. 125-2 (Exhibit A to Alvogen’s Motion) at 1-2. Alvogen concedes that these initial contentions “set forth a single-actor infringement theory for every asserted claim of the ’760 patent.” Motion at 1, *see also* 5 (“Pernix previously asserted a single actor infringement theory”).

In line with its Complaint and initial contentions, Pernix sought a construction of the term “administering” to mean acts of “prescribing, dispensing, giving or taking (such that what is prescribed, dispensed, given or taken is actually taken into the patient’s body).” *See* D.I. 60 at 7. Under Pernix’s proffered construction, the claims could be infringed either by patients taking Alvogen’s ANDA product or by physicians prescribing that product to patients. The Court, however, adopted a narrower construction and found that “administering” meant “delivering into the body.” D.I. 69 at 1. Under the Court’s construction, the only actor who can “administer” Alvogen’s ANDA product is the patient.

Following the Court’s claim construction decision, Pernix served its amended infringement contentions on October 20, 2017. D.I. 125-3 (Exhibit B to Alvogen’s Motion). Alvogen wrongly contends that Pernix made the “deliberate decision to drop” its single-actor theory for ’760 patent claims 1-4 and 11 in these amended contentions. Motion at 5, *see also* 1 (“Pernix amended its infringement contentions by replacing its single-actor infringement theory with a joint infringement theory”). Pernix’s amended contentions for ’760 patent claims 1-4 and

11 did not remove or replace anything. *Compare* D.I. 125-2 at Exhibit A *with* D.I. 125-3 at Exhibit A; *see* Ex. C (side-by-side comparison of Pernix’s initial and amended contentions for ’760 patent claims 1-4 and 11). For example, the amended contentions for ’760 patent claim 1 are identical to the initial contentions apart from the **addition** of the following sentences to make clear that, even under a two-actor theory, physicians would still infringe the claim by directing and controlling a patient to take Alvogen’s ANDA product:

Physicians direct and/or control their patients’ administration of a starting dose of Alvogen’s proposed generic product in such a manner as to condition the receipt of treatment on the patients’ administration of the prescribed starting dose. Further, the physician establishes the manner and timing of the patients’ administration of the starting dose.

D.I. 125-3 at Exhibit A; Ex. C at 1-2.

Alvogen’s confusion likely is of its own making. On the same day that Pernix filed its amended contentions, Alvogen filed its supplemental interrogatory responses in which **Alvogen** unilaterally decided that ’760 patent claims 1-4 and 11 could **only** be jointly infringed by two actors (“Alvogen’s joint infringement defense”):

To the extent ***both of the claimed steps*** would actually be performed, ***different actors would perform those separately claimed steps of selecting a starting dose*** (physician) and ***administering the capsule*** ANDA Product (patient). Under the applicable law governing such situations of “divided” infringement, Pernix must prove that a doctor will direct or control a patient’s performance of the administering step[.]

Ex. A (Alvogen’s Supplemental Interrogatory Responses, dated Oct. 20, 2017) at 9. While Alvogen concluded that the claimed methods have two steps and can only be infringed by two actors, that conclusion does not follow from the Court’s claim construction decision and Pernix has never acquiesced to it. For example, Pernix’s expert Dr. Gudín responded to Alvogen’s joint infringement defense in his expert report, stating:

*if* no single actor performs all steps of the method of treatment claims (*e.g.*, a physician determines the dose to be administered, but the patient self-administers the drug), direct infringement occurs if the acts of one actor are attributable to the other.

D.I. 125-4 (Gudin Opening Infringement Rept.) at ¶ 49 (emphasis added). Dr. Gudin also cited to Alvogen’s supplemental interrogatory responses, which contended that the claims can *only* be jointly infringed:

I further understand that *Alvogen argues that it does not infringe* the claims of the ’760 Patent *because* “different actors would perform [the] separately claimed steps of selecting a starting dose (physician) and administering the capsule ANDA Product (patient).”

*Id.* at ¶ 72 (emphasis added) (citing Alvogen’s Supplemental Interrogatory Responses, dated Oct. 20, 2017, at 9). Thus, while Alvogen revised its interrogatory responses to assert that the claims can only be infringed by two actors, neither Pernix nor its expert have ever agreed or acquiesced to that contention.

In sum, Alvogen’s Motion should be denied because Pernix has not asserted a “new” infringement theory.

**IV. Even If Pernix Raised A New Infringement Theory, The Pennypack Factors Demonstrate That It Should Not Be Excluded**

Alvogen’s Motion should also be denied because none of the *Pennypack* factors support excluding Pernix from arguing single-actor infringement of ’760 patent claims 1-4 and 11.

**A. There Is No Surprise Or Prejudice To Alvogen**

The first *Pennypack* factor is “the surprise or prejudice to the moving party[.]” *See* Section II. Alvogen alleges two points of prejudice.

First, Alvogen argues that had Pernix not allegedly dropped its single-actor theory, Alvogen would have had the “opportunity to respond to this theory in its rebuttal report on non-infringement.” Motion at 4. This argument fails because there are no issues of fact relating to

the single-actor theory. Rather, as explained in Pernix’s Motion for Summary Judgment, the only potential issue as to this theory relates to interpretation of claims 1-4 and 11. Namely, is the “administering” language the only “step” in those claims. *See* D.I. 120 at 12-13 (Explaining that Judge Sleet recognized that the “wherein the starting dose is not adjusted” limitation is integral to the claims because it has “*an effect on how the administering step is performed*” and “patients with hepatic impairment ingest a different dose than they normally would, given the prior art,” but that does not make it a separate “step” in the claims.). If so, as a matter of law Alvogen induces infringement.

That is because Alvogen and its expert *do not dispute* patients will infringe claims 1-4 and 11 because: (1) patients with mild or moderate hepatic impairment will administer Alvogen’s ANDA product, (2) that product meets the claim limitations, and (3) the dose prescribed by physicians will be unadjusted for those patients compared to patients without hepatic impairment. D.I. 120 at Section IV(C)(1); *see generally* D.I. 143 (not disputing direct infringement if claims require one actor).<sup>1</sup> Alvogen provides no explanation as to what opinions its expert could have offered on this legal question of claim interpretation.<sup>2</sup>

Second, Alvogen claims prejudice because had Pernix “reassert[ed]” its single-actor theory prior to the deposition of Pernix’s expert, Dr. Gudin, “it would have shaped Alvogen’s approach to the deposition of [Dr. Gudin] and sparked new questions[.]” Motion at 4. This argument fails at least because Alvogen was put on notice of the single-actor theory almost three

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<sup>1</sup> As Pernix’s Motion also explains, Alvogen likewise infringes if the claims require two actors. D.I. 120 at Section IV(C)(2).

<sup>2</sup> During the deposition of Alvogen’s infringement expert, Dr. Candiotti, Alvogen’s counsel objected to a line of questioning regarding the number of steps in ’760 patent claim 1 on the grounds that Pernix was “asking a non-lawyer to delineate method steps[.]” Ex. B at 116:11-15. If these questions were inappropriate to ask an expert at a deposition, as Alvogen contends, then they are equally as inappropriate to raise in an expert report.

weeks before Dr. Gudin's deposition, when it was raised during the deposition of Alvogen's infringement expert, Dr. Candiotti. During Dr. Candiotti's deposition, Pernix's counsel pursued a line of questioning as to whether "[t]he patient will be practicing every single step in '760 patent claim one[.]" See Ex. B at 52:18-19; 54:12-15 ("Q. . . . Can you tell me a single aspect of '760 patent claim one . . . that the patient will not be practicing?"); 109:4-5 ("Q. . . . [T]he patient can directly infringe, right?"); 109:19-23 ("Q. . . . My question is: Can the patient as an individual . . . directly infringe '760 patent claim one if they take a pill as prescribed by the physician?"); 111:8 ("Q. A patient is a single entity, right?"). Alvogen's counsel repeatedly attempted to shut down questioning on that topic by making improper speaking objections, coaching the witness, threatening to call the judge, and finally leaving the room with the witness to take a break without first consulting the attorney taking the deposition. Ex. B at 118:24-119:10, 122:10-25, 132:14-19; 137:12-18. Alvogen's strident attempts to avoid questioning on the single-actor topic occurred almost three weeks before it deposed Pernix's expert Dr. Gudin. During that three-week period, Alvogen did not raise any issue regarding single-actor infringement, and then made a strategic decision not to ask Dr. Gudin a single question at his deposition about whether performance of the claimed methods requires two actors or only one.

For the foregoing reasons, Alvogen has failed to establish surprise or prejudice, and this factor thus supports the denial of Alvogen's Motion.

**B. Any Prejudice Can Be Cured**

The second *Pennypack* factor is "the ability of the moving party to cure any such prejudice." See Section II. As explained above, there is no prejudice to Alvogen. Even if there were, Alvogen has not established that any such prejudice could not be cured. Alvogen merely concludes that it will "inevitabl[y]" incur "delay and additional expense[.]" Motion at 4-5.

Alvogen is wrong for a number of reasons.

First, Alvogen argues that fact discovery must be reopened. Motion at 4-5. But fact discovery closed on October 20, 2017 (D.I. 71), the same day that Pernix served its amended contentions (D.I. 125-3 at 1-2) in which Alvogen alleges Pernix “replac[ed]” its single-actor infringement theory (Motion at 1). Alvogen was therefore on notice of Pernix’s theory for the entirety of fact discovery and has no basis for its reopening.

Second, Alvogen argues that expert discovery must be reopened. Motion at 4-5. But as explained above, the only question that Pernix allegedly reasserted in its Motion for Summary Judgment is the legal question of whether ’760 patent claims 1-4 and 11 can be infringed by a single actor. It is unclear what opinions Alvogen’s expert could offer on this legal question and, as explained above, Alvogen had the opportunity to cure any alleged prejudice by questioning Pernix’s expert on this issue at his deposition, but strategically chose not to do so.

Third, Alvogen essentially admits that any prejudice could be cured if it is allowed to file a supplemental expert report (Motion at 4-5), but that Alvogen would be prejudiced because of cost. But the cost of any such report would be the same regardless of when Pernix first argued single-actor infringement, and Alvogen has not asserted otherwise. Cost therefore does not constitute prejudice arising from Pernix’s allegedly late disclosure.

Fourth, any prejudice to Alvogen *has already been cured* given that Alvogen has addressed single-actor infringement in its Brief in Opposition to Plaintiffs’ Motion for Summary Judgment of Infringement. *See UCB, Inc. v. KV Pharm. Co.*, 692 F. Supp. 2d 419, 422 (D. Del. 2010) (“The Court finds on the record presented that Plaintiffs are not prejudiced by the late assertion of the defense as seen by their ability to respond to Defendant’s Summary Judgment Motion on the issue.”). *See* D.I. 143 at Section IV(B)(1) (“[T]his section explains why Pernix’s single-actor infringement theory . . . fails as a matter of law.”).

Alvogen has failed to establish that any prejudice cannot be cured, and this factor thus supports the denial of Alvogen's Motion.

**C. Trial Will Not Be Disrupted**

The third *Pennypack* factor is “the extent to which allowing the testimony would disrupt the order and efficiency of trial.” *See* Section II. This factor also supports the denial of Alvogen's Motion. Alvogen vaguely argues that it will have to “revamp its trial strategy,” but does not allege that doing so will disrupt trial. Moreover, Alvogen's claim that it will take a “significant amount of time” to “revamp” its trial strategy is unsupported and contradicted by Alvogen's argument that Pernix's single-actor theory is unimportant because it is only “a *single* infringement theory for a *single* subset of claims in *one* asserted patent.” Motion at 3 (emphasis added). Alvogen fails to explain why it would take a “significant amount of time” to address the legal question of whether '760 patent claims 1-4 and 11 can be infringed by a single actor. Moreover, Alvogen's concern arose more than two months before trial, providing it more than enough time to make any minor adjustments to its trial strategy that it may believe are necessary.

**D. Alvogen Does Not Allege Bad Faith**

The fourth *Pennypack* factor is “bad faith or willfulness in failing to comply.” Exclusion of an infringement theory is an extreme sanction, not normally imposed absent a showing of willful deception or flagrant disregard of a court order. *See* Section II, above (citing *Indivior Inc.*; *EON Corp.*; *Abbott Labs.*; *AVM Techs*). Alvogen concedes that it is not accusing Pernix of acting willfully or in bad faith (Motion at 5-6). In fact, as explained above, Pernix's Motion for Summary Judgment does not raise a “new” infringement theory.

Thus, because Alvogen does not allege that Pernix has acted in bad faith or willfully failed to comply with any discovery order, let alone established that Pernix has acted with the

“egregious” behavior required for this factor to support exclusion, *Withrow v. Spears*, 967 F. Supp. 2d 982, 1006-7 (D. Del. 2013), Alvogen’s Motion should be denied.

**E. Pernix’s Infringement Theory Is Important**

The last *Pennypack* factor is “the importance of the testimony sought to be excluded.” *See* Section II. Alvogen’s argument that this factor favors exclusion because “Alvogen only seeks to exclude a single infringement theory for a single subset of claims in one asserted patent” (Motion at 3) misses the point. Alvogen seeks to sell infringing generic copies of Pernix’s Zohydro<sup>®</sup> ER product before the patents covering that product expire. Pernix must prove infringement in order to obtain an injunction to stop Alvogen from damaging the market for Zohydro<sup>®</sup> ER. Each of Pernix’s infringement theories is therefore important, and absent a determination by the Court that any one infringement theory is unnecessary, excluding any one of them is an extreme sanction. Courts in the Third Circuit have repeatedly characterized infringement theories, contentions, and/or expert reports as “critical evidence,” the exclusion of which is an “extreme sanction.” *See* Section II (citing *Indivior Inc.*; *EON Corp.*; *Abbott Labs.*; *AVM Techs.*).

**V. Conclusion**

For the foregoing reasons, Pernix respectfully requests that Alvogen's Motion be denied.

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April 9, 2018

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## Exhibit A

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## Exhibit B

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## Exhibit C

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**CERTIFICATE OF SERVICE**

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on April 9, 2018 on the following counsel in the manner indicated:

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